Calendar No. 283

98TH CONGRESS *1st Session*	SENATE	REPORT No. 98-177

SMOKING PREVENTION HEALTH AND EDUCATION ACT OF 1983

REPORT

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

TO ACCOMPANY

S. 772

together with

ADDITIONAL AND MINORITY VIEWS

JULY 13 (legislative day, JULY 11), 1983.—Ordered to be printed

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Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

together with

ADDITIONAL AND MINORITY VIEWS

[To accompany S. 772]

The Committee on Labor and Human Resources, to which was referred the bill (S. 772) to promote public health by improving public awareness of the health consequences of smoking and to increase the effectiveness of Federal health officials in investigating and communicating to the public necessary health information, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

I. SUMMARY OF THE BILL

As reported by the Committee, S. 772 would amend the Public Health Service Act (PHSA) and the Federal Cigarette Labeling and Advertising Act. The bill creates a new section 1711 of the PHSA which directs the Secretary of the Department of Health and Human Services to establish a program to inform the public of the dangers to health associated with cigarette smoking. The Secretary, acting through a newly established Interagency Committee on Smoking and Health (created under new section 1711(b)) is directed to coordinate all other activities of the Federal Government which relate to smoking and health. The Interagency Committee will also

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coordinate the activities of the Federal Government with similar activities in the private sector. The Secretary will conduct research and develop new methods to inform the public of the health consequences associated with smoking. The Secretary would also be responsible for the dissemination of information and related data on the health effects of smoking. This information will be made available through numerous sources, including specific publications, bibliographies and reference materials, and information on research efforts into the effects of smoking on health. Finally, the Secretary is directed to undertake additional informational and research activities that the Secretary determines to be necessary and appropriate, and seek methods of communication with Federal, State, and local entities and the private sector.

The newly established Interagency Committee on Smoking and Health will be comprised of members from the Department as well as representatives from the National Institutes of Health, the Health Resources and Services Administration, and the Centers for Disease Control. The Committee will meet no less than four times a year. The Secretary is directed to transmit a report to the Congress each year which will contain current information on smoking and health, Federal and private sector activities in the area, and recommendations for legislation that the Secretary considers appropriate.

The bill further amends Title XVII of the Public Health Service Act by adding a new section 1712 to establish a cigarette "additive" reporting system. All persons who manufacture, import or package cigarettes for sale or distribution within the U.S. will have to provide the Secretary of Health and Human Services with a complete list of each chemical additive and the quantity of the additives used in the manufacture of such cigarettes. This information may not be disclosed by the Secretary or any officer or employee of the Department. Persons who violate the provisions of the disclosure prohibition will be guilty of a misdemeanor and upon conviction be subject to a fine of not more than $10,000. The district courts of the U.S. can prevent and restrain violations of the additive information subsection upon the application of the Attorney General. Annually, the Secretary will transmit to the Congress a report which must include a complete listing of chemical additives used in the manufacture of cigarettes, a summary of research activities and research findings on the health risks associated with such additives, information pertaining to additives which may pose an additional health risk to cigarette smokers, and any other information which the Secretary believes to be in the public interest. No information in the report will identify which individual additives are used in any specific brand of cigarettes or by any specific person who manufactures, imports or packages cigarettes for sale or distribution in the U.S.

S. 772 amends the Federal Cigarette Labeling and Advertising Act to change the warning statement required on cigarette packages to read: "WARNING! Cigarette smoking causes CANCER, EMPHYSEMA, and HEART DISEASE, may complicate PREGNANCY, and is Addictive." It also requires that a cigarette package disclose the level of tar, nicotine, and carbon monoxide contained in such cigarettes.

II. Background and Need for Legislation

> Cigarette smoking is clearly the single most important preventable cause of premature illness and death in the United States. Estimates of the number of deaths related to smoking exceed 300,000 annually. One may compare this figure with the 105,000 deaths that occur each year as a result of injuries, 20,000 deaths from homocides, or the 40,000 infant deaths.

This was the testimony of the Assistant Secretary of HHS for Health, Dr. Edward N. Brandt, Jr., before this Committee on March 16, 1982. Dr. Brandt went on to give a capsule description of our current knowledge of the health effects of cigarette smoking:

> Cigarette smoking is one of the three major independent risk factors of coronary heart disease and for arteriosclerotic peripheral vascular disease. It is a major cause of cancer of the lung, larynx, oral cavity, and esophagus and a major cause of chronic bronchitis and emphysema.
>
> Maternal cigarette smoking is associated with retarded fetal growth, an increased risk for spontaneous abortion and for prenatal death, and slight impairment of growth and development during early childhood.
>
> Cigarette smoking acts synergistically with oral contraceptives to enhance the probability of coronary and some cerebrovascular disease; with alcohol to increase the risk of cancer of the larynx, oral cavity, and esophagus; with asbestos and some other occupationally encountered substances to increase the likelihood of cancer of the lung; and with other risk factors to enhance cardiovascular risk.

This accumulation of knowledge, which amounts to a strong indictment of cigarette smoking as a cause of illness, disability, and death, comes after more than twenty years of Federal activity in the area of smoking and health.

On June 7, 1962, the Surgeon General of the Public Health Service appointed an advisory committee to study all published literature bearing on the relationship of smoking to health. After studying the problem for 18 months, the committee submitted a report to the Surgeon General on January 11, 1964. The unanimous judgment of the Surgeon General's Advisory Committee on Smoking and Health was that: "Cigarette smoking is a health hazard of sufficient importance in the United States to warrant remedial action." The report went on to link cigarette smoking specifically with the incidence of and mortality from lung cancer, chronic bronchitis and emphysema, and cardiovascular diseases.

In an effort to take the "appropriate remedial action", the 89th Congress enacted, on July 27, 1965, the Federal Cigarette Labeling and Advertising Act, Public Law 89-92. This legislation required each cigarette package to bear the warning: "Caution: Cigarette Smoking May Be Hazardous to Your Health." The 1965 act also required the Secretary of Health, Education and Welfare and the Federal Trade Commission to submit periodic reports and recommendations to the Congress.

In addition to this legislation enacted in response to the Advisory Committee's report, other actions were taken by the Federal Government and by the private sector to educate the public about the dangers of smoking. The Public Health Service developed programs for the public as well as professionals on smoking education and also established a national clearinghouse on smoking and health information. In addition, State and local health and education authorities and the major voluntary health organizations, launched vigorous smoking education programs.

The next landmark in the history of Federal action on smoking and health came in 1969 and 1970 when the 91st Congress considered and passed legislation relating to cigarette labeling and advertising. The Public Health Cigarette Smoking Act of 1970, Public Law 91-222, which was signed into law on April 1, 1970:

(1) Changed the cigarette package label wording to "Warning: The Surgeon General has Determined that Cigarette Smoking is Dangerous to Your Health"; and

(2) Prohibited advertising of cigarettes on radio and television beginning January 2, 1971.

The 1970 act also required annual reports to Congress by the FTC and the Department of Health, Education and Welfare on the health consequences of smoking, effectiveness of labeling and advertising practices.

In August of 1970, the FTC issued a proposed rule to require cigarette manufacturers to disclose tar and nicotine content of cigarettes in their print advertising. The proceeding was suspended in December of the same year when cigarette manufacturers agreed voluntarily to make the disclosures. By December 1971, all cigarette advertisements included tar and nicotine content information.

In the years after the 1970 legislation, the Department of Health, Education and Welfare, now the Department of Health and Human Services, continued to collect and evaluate the information and data from research carried out nationally and worldwide on the relationship between smoking and the incidence of various diseases. These research reports and evaluations have been summarized by the Surgeon General in annual reports entitled "The Health Consequences of Smoking," which have made an important contribution to the body of scientific knowledge and synthesize the vast amount of scientific data relating smoking directly to specific diseases.

The fourteenth report of the Surgeon General, published in 1981, came as a direct response to a Congressional request. The Health Services and Centers Amendments of 1978, Public Law 95-626, enacted in November of 1978, included a provision, section 403, which directed the Secretarty of HEW to conduct a "study of studies of (1) the relative health risks associated with smoking cigarettes of varying levels of tar, nicotine, and carbon monxide; and (2) the health risks associated with smoking cigarettes containing any substances commonly added to commercially manufactured cigarettes."

The 1981 Surgeon General's report, subtitled The Changing Cigarette, addressed this issue of the potential hazards of substances added to cigarettes. In her introduction to the report, then-Secretary of HHS Patricia Roberts Harris noted "the need to know about substances added to cigarettes is stated repeatedly. At present, there is no mechanism by which government or the scien-

tific community can require disclosure of these additives, which must obviously be a first step in assessing their health effects. This needs to be corrected by voluntary action or, if necessary, by legislation."

One of the basic findings of the 1981 report questioned the use of additives—"whether the new cigarettes being produced today introduced new risks through their design, filtering mechanisms, tobacco ingredients, or additives." The Public Health service had been unable "to assess the relative risks of cigarette addi;ies because information was not available from manufacturers as to what these addtives are."

The 1981 report went on to note that "no agency of the Federal Government currently exercises oversight or regulatory authority in the manufacture of cigarette products. Further, no agency is empowered to require public or confidential disclosure of the additives actually in use by the cigarette manufacturers," and suggests the possibility of working out procedures to enable cigarette manufacturers to disclose additives "while still protecting their legitimate interests in trade secrets."

Finally, the 1981 Surgeon General's report recommended that "flavoring agents and additives should be studied by cigarette companies for carcinogenicity and toxicity before their commercial use is permitted, and the results of such studies should be made available."

The 1982 edition of the Surgeon General's report on the Health consequences of smoking addressed the issue of the relationship between smoking and a single disease—cancer. This report stands as the strongest indictment to date of smoking as a significant causal factor in the development of several kinds of cancer. In his foreword to the report, Dr. Edward Brandt, Assistant Secretary of HHS for Health, describes cigarette smoking as "the major single cause of cancer mortality in the United States." The Surgeon General, Dr. C. Everett Koop, in his preface describes cigarette smoking as "the chief, single avoidable cause of death in our society and the most important public health issue of our time."

The 1982 report states that cigarette smoking is a major cause of cancers of the lung, larynx, oral cavity, and esophagus, and is a contributory factor for the development of cancers of the bladder, pancreas, and kidney. The "contributory factor" by no means excludes the possibility of a causal role of smoking in cancer of these types.

Cancer has been the second most comman cause of death in the United States and the United States and accounts for an estimated 430,000 deaths annualy. Furthermore, the report estimates that tobacco's contribution to all cancer related deaths is 30 percent, with cigarette smokers having total cancer rates twice that of nonsmokers. This means that 129,000 Americans will die of cancer this year because of higher overall cancer death rates existing among smokers as compared to nonsmokers.

The long-range goal of the Federal Government's anti-smoking effort, is to elimate the premature deaths, diosabilities, and health care costs associated with cigarette smoking. Not only is cigarette smoking associated with approximately 300,000 deaths each year, but health care costs are estimated to ber $12–13 billion annually

due to smoking. The Department of HHS estimates that $25 billion in productivity is lost annually as a result of smoking. Although the percentage of adult smokers in the population (32.6 percent) is at its lowest level in 45 years, 54 million Americans still smoke and 3.5 million adolescents between 12 and 18 year of age are current regular smokers.

The Department's efforts to reduce or eliminate the consequences of smoking focus on specific programs designed to:

Educate cigarette smokers in the general population as to the health risks of smoking.

Educate women who smoke, especially those who are pregnant, take oral contraceptives, or have increased risk of disease due to other factors of the adverse health effects of their smoking.

Educate children and adolescents of the adverse health effect of taking up smoking.

Educate persons exposed to occupational health hazards, including asbestos, of the additional health risks if they smoke.

Collect information pertaining to the prevalence, attitudinal, epidemiologic, economic factors and any other data on smoking, for the purpose of futher research, planning, and evaluation.

In May 1981, the Federal Trade Commission published a staff report on its investigation of cigarette advertising. The report found that past efforts of the FTC, the Congress, and other government agencies and private organizations to increase the amount of information on the hazards of cigarette smoking available to consumers have had an important impact. According to the report, many more consumers at the present time are aware that smoking is hazardous to their health than were in 1964, at the time of the first Surgeon General's report. The percentage of Americans who smoke cigarettes has declined significantly over the same time period, and a substantially larger number of those who do smoke now smoke cigarettes with lower levels of "tar" in nicotine.

Despite this, the FTC staff report found that the problems which prompted the Commission to act on smoking and health in the past still existed. For instance, while most Americans are aware generally that smoking is hazardous, some consumers, smokers in particular, do not know this basic fact. In addition, according to the FTC, the evidence indicates that many consumers do not have enough information about the health risks of smoking to know how dangerous smoking is, i.e., what is the nature and extent of the health risks of smoking.

The data discussed in the FTC report indicate that many Americans still do not know what specific diseases are related to smoking. For example, the report cites polls showing that over 30 percent of the public was unaware of the relationship between smoking and heart disease. Nearly 50 percent of all women did not know that smoking during pregnancy increases the risk of stillbirth and miscarriage. Approximately 30 percent of those polled did not know about the relationship between smoking, birth control pills, and the risk of heart disease. Even for lung cancer, which was the first and is probably the best-known, disease associated with smoking, it was clear that gaps still remain in consumer knowledge

about smoking—20 percent of those polled did not know that smoking causes cancer.

The apparent gap between current scientific knowledge about the health risks of smoking and the lack of specific consumer understanding of these risks led FTC staff to conclude that the current warning statement on cigarette packages and in advertisements is ineffective. The report concludes that additional action designed to provide consumers with more specific information about the health consequences of smoking is necessary. Of the numerous options considered to accomplish this, the report concludes that the actions most likely to be effective would be: (1) Additional funding for expanded educational efforts, such as public service announcements; (2) changing the shape and increasing the size of the current warning; and (3) replacing the current warning with a system of short rotational warnings.

These options have been addressed and further incorporated into a single strong warning label, agreed upon by the Labor and Human Resources Committee.

III. Text of S. 772 as Reported

[S. 772, 98th Cong., 1st sess.]

A BILL To promote public health by improving public awareness of the health consequences of smoking and to increase the effectiveness of Federal health officials in investigating and communicating to the public necessary health information, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Smoking Prevention Health and Education Act of 1983".

FINDINGS

Sec. 2. The Congress finds that—

(1) cigarette smoking is the largest preventable cause of illness and premature death in the United States, and is associated with the unnecessary deaths of over three hundred thousand Americans annually;

(2) smoking is the primary cause of lung cancer and emphysema in the United States, and is associated with other cancers;

(3) heart disease accounts for nearly one-half of the deaths in the United States, and one-third of the deaths attributable to heart disease are associated with smoking;

(4) the risks of miscarriage, stillbirths, premature births, and child weight deficiencies for pregnant women who smoke are higher than for pregnant women who do not smoke; and

(5) present Federal, State, and private initiatives have been insufficient in conveying to the American public the information contained in paragraphs (1) through (4) of this section and other information regarding smoking.

PURPOSE

SEC. 3. It is the purpose of this Act to promote public health by providing health information to the American public that will allow individuals to make informed decisions concerning smoking.

SMOKING RESEARCH, EDUCATION, AND INFORMATION

SEC. 4. (a) Title XVII of the Public Health Service Act is amended by adding at the end thereof the following new section.

"SMOKING AND HEALTH

"SEC. 1711. (a) The Secretary shall establish and carry out a program to inform the public of the dangers to health from cigarette smoking. In carrying out such program, the Secretary shall—

"(1) coordinate all activities of the Department which relate to smoking and its effects on health, including research and demonstration projects and educational activities;

"(2) through the Interagency Committee on Smoking and Health established under subsection (b), coordinate the activities referred to in paragraph (1) of this subsection with all other activities of the Federal Government which relate to smoking and its effects on health;

"(3) through the Interagency Committee on Smoking and Health established under subsection (b), coordinate the activities of the Federal Government referred to in paragraphs (1) and (2) of this subsection with similar activities in the private sector;

"(4) conduct research and develop new methods for informing the public of the effects of smoking on health, either independently or in conjunction with the private sector, for use in a national effort;

"(5) collect, analyze, and disseminate information, studies, and other data related to smoking and its effects on health;

"(6) make available, through specific publications and bibliographic and reference materials, information on research efforts relating to smoking and its effects on health; and

"(7) undertake any other additional informational and research activities which the Secretary determines necessary and appropriate.

In carrying out the requirements of this subsection, the Secretary shall seek to develop methods of communication with Federal, State, and local entities, as well as with the private sector.

"(b)(1) To carry out the activities described in paragraphs (2) and (3) of subsection (a), there is established an Interagency Committee on Smoking and Health. The Committee shall be composed of representatives from appropriate institutes and agencies of the Department, which may include the National Heart, Lung, and Blood Institute, the National Cancer Institute, the National Institute of Child Health and Human Development, the Health Resources *and* Services Administration, and the [Center] *Centers* for Disease Control.

"(2) The Committee shall meet at least four times each year.

"(c) The Secretary shall transmit a report to Congress not later than January 1 of each year which shall contain—

"(1) current information on the effects of smoking on health;

"(2) an overview and assessment of Federal activities undertaken to inform the public of the effects of smoking on health;

"(3) information regarding the activities of the private sector with respect to the effects of smoking on health; and

"(4) such recommendations for legislation as the Secretary may consider appropriate.".

(b) Section 8 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1337) is amended by striking *out* subsection (a) and by striking *out* the subsection designation "(b)".

ADDITIVE INFORMATION

SEC. 5. Title XVII of the Public Health Service Act (as amended by section 4(a) of this Act) is further amended by adding at the end thereof the following new section:

"ADDITIVE INFORMATION REQUIRED

"SEC. 1712. (a)(1) It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes unless such person has provided to the Secretary a complete list of each chemical additive used in the manufacture of such cigarettes and the relative quantity of such additives.

"(2) The Secretary and any officer or employee of the Department shall not disclose to any person outside the Department any information received pursuant to paragraph (1).

"(3) For purposes of section 552(b)(4) of title 5, United States Code, and section 1905 of title 18, United States Code, any information received by the Secretary or any officer or employee of the Department pursuant to paragraph (1) shall be considered to be a trade secret.

"(b) Any person who violates the provisions of subsection (a)(1) of this section shall be guilty of a misdemeanor and shall, upon conviction thereof, be subject to a fine of not more than $10,000.

"(c) Upon application of the Attorney General of the United States, the district courts of the United States shall have jurisdiction, for cause shown, to prevent and restrain violations of subsection (a)(1) of this section.

"(d) At such times as the Secretary considers appropriate, but not less than annually, the Secretary shall transmit to the Congress a report which shall include a complete listing of chemical additives used in the manufacture of cigarettes based on the additive information required to be submitted under subsection (a)(1), a summary of research activities and research findings on the health risks associated with such additives, information pertaining to any such additive or additives which in the judgment of the Secretary pose an additional health risk to cigarette smokers, and any other information which the Secretary determines to be in the public interest, except that no information contained in any such report shall identify which individual additives are used in any specific brand of cigarettes or by any specific person who manufactures

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cigarettes, imports cigarettes, or packages cigarettes for sale or distribution within the United States.".

PUBLIC AWARENESS

SEC. 6. Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"PUBLIC AWARENESS [STATEMENTS] *STATEMENT*

"SEC. 4. (a)(1) It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes, the package of which fails to bear one of the following [statements] *statement:*

[]"(A) 'WARNING: The Surgeon General has Determined Cigarette Smoking Causes Lung Cancer and Emphysema, and Is a Major Cause of Heart Disease.';

[]"(B) 'WARNING: The Surgeon General has Determined Cigarette Smoking by Pregnant Women May Result in Miscarriage, Premature Births, and Low Birth Weight Babies.';

[]"(C) 'SMOKERS: No Matter How Long You Have Smoked, Quitting Now Greatly Reduces the Risks to Your Health; For more information, write: Surgeon General, U.S. Public Health Service, Washington, D.C. 20201.';

[]"(D) 'TEENAGERS: Smoking is Addictive. Never Starting Means Never Having to Quit.'.

" *'WARNING: Cigarette smoking causes CANCER, EMPHYSEMA, and HEART DISEASE; may complicate PREGNANCY; and is ADDICTIVE.'.*

[]"(2) The labeling statements specified in paragraph (1) of this subsection shall be rotated on the packages of each brand of cigarettes in a manner that assures that each of such labeling statements appears a substantially similar number of times on each brand of cigarettes within the twelve month period beginning on the effective date of this subsection and each succeeding twelve month period.]

[]"(3) Any] *(2) The* labeling statement required under this subsection shall be located in a conspicuous place on every cigarette package and shalll appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.

[]"(4) In accordance with the provisions of section 553 of title 5, United States Code, the Federal Trade Commission shall establish by rule a system to ensure that labeling statements required under this subsection are rotated in accordance with the provisions of paragraph (2) of this subsection, and that at any time each of the four labeling statements appears a substantially similar number of times on all cigarette packages.]

"(b)(1) It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes, the package of which fails to disclose the level of—

"(A) tar;

"(B) nicotine; and

"(C) carbon monoxide;

contained in such cigarettes.".

SEPARABILITY

SEC. 7. If any provision of this Act or the amendments made by this Act or the application thereof to any person or circumstances is held invalid, the other provisions of this Act and the application of such provisions to other persons or circumstances shall not be affected thereby.

EFFECTIVE DATE

SEC. 8. The provisions of this Act and the amendments made by this Act shall take effect on the date of enactment of this Act, except that the amendment made by section 5 of this Act shall take effect one year after the date of the enactment of this Act and the amendment made by section 6 of this Act shall take effect on January 1, April 1, July 1, or October 1, whichever first occurs, after the date which is one year after the date of the enactment of this Act.

IV. HEARINGS

Hearings were held May 5, 1983 and testimony heard from:

Mrs. Barney Clark (Una Loy Clark), Des Moines, Washington;

Dr. Edward N. Brandt, Assistant Secretary for Health, Department of Health and Human Services;

Dr. Claude Lenfant, Director of the National Heart, Lung and Blood Institute;

Dr. Mortimer B. Lipsett, Director of the National Institute of Child Health and Human Development;

Dr. William Pollin, Director of the National Institute on Drug Abuse;

Dr. Jane Henney, Deputy Director of the National Cancer Institute;

Dr. JoAnn Luoto, Acting Director of the Office of Smoking and Health;

Dr. Virginia Ernster, Associate Professor of Epidemiology, University of California—San Francisco;

Dr. Lawrence Longo, Head of the Division of Perinatal Biology, Professor of Physiology, Obstetrics and Gynecology, Loma Linda Unversity School of Medicine, Corona, California, representing the American Academy of Pediatrics and the American College of Obstetrics and Gynecology;

Dr. Robert A. Sandhaus, Senior Staff Physician, Associate Professor of Medicine, University of Colorado Health Sciences Center, Denver, Colorado;

Mr. Robert Keeshan, Executive Producer of Robert Keeshan Associates, (Captain Kangaroo);

Dr. William Cahan, Professor of Surgery, Cornell University Medical College, Attending Surgeon, Thoracic Service, Memorial Hospital, The Memorial Sloan-Kettering Cancer Center, representing the American Cancer Society, New York, New York;

Dr. John Oates, Professor of Medicine and Pharmacology, Department of Medicine, Vanderbilt University, Nashville, Tennessee,

Chairman of the Subcommittee on Smoking of the American Heart Association, representing the American Heart Association; and

Dr. Edwin Fisher, Associate Professor of Psychology, Washington University, St. Louis, Missouri, representing the American Lung Association.

Hearings were held May 12, 1983 and testimony heard from:

Curtis H. Judge, Lorillard, Chairman of the Executive Committee of The Tobacco Institute, New York, New York;

Sheldon C. Sommers, M.D., Lenox Hill Hospital, New York, New York;

Edwin R. Fisher, M.D., Shadyside Hospital, Pathology Laboratory, Pittsburgh, Pennsylvania;

Roger D. Blackwell, Ph.D., Professor of Marketing, Ohio State University, Columbus, Ohio;

Theodore H. Blau, Ph.D., Tampa, Florida; and

Eric Rubin, Esq., Rubin, Winston and Dierks, Counsel for the Outdoor Advertisers Association of America, Washington, D.C.

V. Committee Views

The Committee endorses the views published by the surgeon general in the 1982 report on smoking and health which state that cigarette smoking is the number one cause of the premature death in the United States. This is strong language, but the evidence implicating cigarette smoking as a causative factor of many diseases is overwhelming. Over 30,000 scientific studies have linked cigarette smoking with various diseases, and the committee believes it is the responsibility of Congress to convey this message to our citizens.

The Committee believes S. 772 is timely and necessary to facilitate a renewed national public education effort to make our citizens more aware of the health consequences of smoking. The Committee does not deem this legislation as regulatory, unduly nor proscriptive of our citizens right to smoke, but simply as an appropriate and necessary federal effort to provide public education. In fact, the Committee believes preventive medicine and health promotion are among the highest priorities of our national health policy, and this legislation is one part of an effort to enhance these activities at the federal level.

Recent estimates put the cost of smoking in excess of $38 billion—the combined cost of lost productivity and providing health care for smoking related illnesses. In fact, almost $4.0 billion are expended under Medicare and Medicaid for treating smoking related illnesses. The Committee believes that this legislation holds the promise of making a major contribution to constraining the dramatic increases in the cost of health care.

The Committee recognizes the work of the major voluntary agencies in bringing this legislation to pass, specifically, the American Heart Association, The American Cancer Society, the American Lung Association, the American College of Obstetricians and Gynecologists and American Academy of Pediatrics, all effectively represented by the Coalition on Smoking or Health. In addition to these organizations, virtually every other health professional and voluntary organization has endorsed this effort. The Committee has ap-

preciated the overwhelming support for this legislation, and has been impressed with the efforts of the many individuals and groups in assisting, in development of this bill.

The Committee recognizes the dissenting views provided in testimony by representatives of The Tobacco Institute, and views expressed in this report by Senator East. However, the Committee believes that the views of the industry represented by Senator East, are primarily related to economic concerns of the tobacco industry, and the scientific evidence provided by them is not supportable.

The Committee recognizes this legislative effort if only a part of what is necessary to educate Americans of the health hazards admitted with smoking, and thereby reduce the numbers of smokers. Continued cooperation among private, public, and voluntary organizations in informing our citizens about the adverse health consequences of smoking is essential to achieve the long-term goal of the Smoking Prevention Health and Education Act of 1983.

VI. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, D.C., June 24, 1983.

Hon. Orrin G. Hatch,
Chairman, Committee on Labor and Human Resources, U.S. Senate, Washington, D.C.

Dear Mr. Chairman: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has reviewed S. 772, the Smoking Prevention Health and Education Act of 1983, as ordered reported by the Senate Committee on Labor and Human Resources on June 22, 1983.

The bill directs the Secretary of Health and Human Services (HHS) to establish and carry out a program to inform the public of the dangers to health from cigarette smoking. It also requires reporting of all chemical additives used in the manufacture of cigarettes, and it modifies the health warning required on cigarette packages. Since the bill authorizes no monies for the activities assigned to HHS, it is assumed that they will be subsumed under current authorizations. Thus, it is expected that no additional costs to the government will be incurred as a result of enactment of this legislation.

Should the Committee so desire, we would be pleased to provide further details on this estimate.

Sincerely,

James Blum,
(For Alice M. Rivlin, *Director*).

Department of Health & Human Services,
Washington, D.C., July 6, 1983.

Hon. Thomas F. Eagleton,
Committee on Labor and Human Resources,
U.S. Senate, Washington, D.C.

Dear Senator Eagleton: It has come to my attention that there may be a misunderstanding about my recent discussions with the

Tobacco Institute concerning a stronger warning label for cigarettes. The purpose of this letter is to indicate my activities in those discussions.

As you know, Senator Hatch asked me and representatives of the tobacco industry to meet to try to reach an agreement on a stronger warning label. As a result of this request, members of my staff and I met on a number of occasions with industry representatives to negotiate an agreement. The only subject discussed at those meetings was a stronger warning label. We did not discuss other aspects of S. 772 or possible amendments to the bill. That was not our goal, and hence, was not on our agenda. I hope this clarifies my participation.

Since the discussion at the mark-up session on June 22 involved the entire Committee membership, I am sending a copy to each member. I will be happy to provide further information to you or other members, should you desire.

I send you my best wishes.

Sincerely,

EDWARD N. BRANDT, Jr., M.D.,
Assistant Secretary for Health.

VII. REGULATORY IMPACT STATEMENT

The Committee has determined there will be minimal increase in the regulatory burden and paperwork associated with this bill.

VIII. TABULATION OF VOTES CAST IN COMMITTEE

Senator Thomas F. Eagleton offered an amendment to replace the multiple, rotating warning labels in the original text of S. 772 with a single, stronger warning label. This amendment was approved by the committee: with a rollcall vote resulting in 15 yes, 1 no, and 2 absent.

A motion to report the bill favorably to the Senate was then passed by a rollcall vote resulting in 14 yes, 1 no, 1 present, and 2 absent.

IX. SECTION-BY-SECTION ANALYSIS

This bill provides that the Act may be cited as the "Smoking Prevention Health and Education Act of 1983.

Section 2 of the bill states the findings of Congress that smoking is a contributing factor to a number of illnesses, diseases, and premature death, and that present Federal, State, and private initiatives have been insufficient in conveying these messages to the American public.

Section 3 of the bill states the purpose of the legislation to provide information that will allow individuals to make informed decisions concerning smoking.

Section 4 of the bill amends Title XVII of the Public Health Service Act (PHSA) by adding at the end a new section 1711. The new section 1711(a) directs the Secretary of Health and Human Services to establish and carry out a program to inform the public of the dangers to health of cigarette smoking. To accomplish this goal, the Secretary shall:

(1) coordinate all activities of the Department which relate to smoking and health, including research, demonstration projects, and educational activities;

(2) coordinate the activities referred to in the first clause with all other activities of the Federal Government through an Interagency Committee on Smoking and Health (which is established under section 1711(b));

(3) through the Interagency Committee on Smoking and Health, coordinate activities of the Federal Government with similar activities in the private sector;

(4) conduct research and development of new methods for informing the public of the effects of smoking and health;

(5) collect, analyze, and disseminate information, and other data related to smoking and health;

(6) make available various materials on research efforts relating to smoking and health; and

(7) undertake any additional research and informational activities that the Secretary determines to be necessary and appropriate.

In carrying out these requirements, the Secretary shall seek methods of communication between Federal, State, and local entities, and the private sector.

The new section 1711(b) establishes the Interagency Committee on Smoking and Health composed of representatives from appropriate institutes and agencies of the Department including the National Heart, Lung, and Blood Institute, the National Cancer Institute, the National Institute of Child Health and Human Development, the Health Resources and Services Administration, and the Centers for Disease Control. The committee shall met at least four times each year.

The new section 1711(c) requires the Secretary to transmit a report to Congress not later than January 1 of each year containing:

(1) current information on the effects of smoking on health;

(2) an overview and assessment of Federal activities undertaken to inform the public about the effects of smoking on health;

(3) information on the activities of the private sector with respect to the effects of smoking on health; and

(4) recommendations for legislation as the Secretary may consider appropriate.

Section 4(b) of the bill amends section 8 of the Federal Cigarette Labeling and Advertising Act by striking the language of that section that requires the Secretary to transmit smoking and health reports to the Congress each year.

Section 5 of the bill also amends Title XVII of the Public Health Service Act by adding a new section 1712. The new section 1712(a) makes it unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes unless that person has provided to the Secretary a complete list of each chemical additive used in the manufacture of such cigarettes, and the relative quantity of such additives. Section 1712(a)(2) prohibits the Secretary or any officer or employee of the Department from disclosing to any person outside the Department any informa-

tion thus received. The new section 1712(a)(3) states that any such information received by the Secretary or any officer or employee of the Department will be considered to be a trade secret.

The new section 1712(d) states that any person who violates subsection (a)(1) shall be guilty of a misdemeanor and shall, upon conviction thereof, be subsect to a fine of not more than $10,000.

The new section 1712(c) invests the district courts of the U.S. with jurisdiction to prevent and restrain violations of the provisions of subsection (a)(1) regarding chemical additives.

The new section 1712(d) requires the Secretary to transmit to the Congress an annual report which shall include a complete listing of chemical additives used in the manufacture of cigarettes. The report shall also contain information on research activities and findings on the health risks associated with such additives, and whether, in the judgment of the Secretary, these additives pose additional risks to cigarette smokers. The report shall also include any other information which the Secretary determines to be in the public interest, with the exception of information which identifies which individual additives are used in any specific brand of cigarettes for sale or distribution within the United States.

Section 6 of the bill amends section 4 of the Federal Cigarette Labeling and Advertising Act to make it unlawful for any person to manufacture, import, or package for sale or distribution in the U.S. any cigarettes, the package of which fails to bear the following statement: WARNING. Cigarette smoking causes CANCER, EMPHYSEMA, HEART DISEASE, may complicate PREGNANCY, and is ADDICTIVE. The bill requires that the labeling statement be located in a conspicuous place on every cigarette package and appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package. It also requires that every cigarette package disclose the level of tar, nicotine, and carbon monoxide contained in such cigarettes.

Section 7 of the bill states that in the event that any provision of the Act or amendments made by the Act or the application thereof to any person or circumstances are held invalid, the other provisions of the Act and amendments made by the Act shall not be affected thereby.

Section 7 of the bill states that the Act and its amendments shall take effect on the date of enactment, except that section 5 regarding additive information reporting shall take effect one year after the date of enactment, and section 6 regarding the public awareness statement shall take effect on the first January 1, April 1, July 1, or October 1 which occurs after the date which is one year after the date of enactment.

X. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standard Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

TITLE I—SHORT TITLE AND DEFINITIONS

SHORT TITLE

SECTION 1. This act may be cited as the "Public Health Service Act."

* * * * * * *

TITLE XVII—HEALTH INFORMATION AND HEALTH PROMOTION

GENERAL AUTHORITY

SEC. 1701. (a) * * *

* * * * * * *

SMOKING AND HEALTH

SEC. 1711. (a) The Secretary shall establish and carry out a program to inform the public of the dangers to health from cigarette smoking. In carrying out such program, the Secretary shall—

(1) coordinate all activities of the Department which relate to smoking and its effects on health, including research and demonstration projects and educational activities;

(2) through the Interagency Committee on Smoking and Health established under subsection (b), coordinate the activities referred to in paragraph (1) of this subsection with all other activities of the Federal Government which relate to smoking and its effects on health;

(3) through the Interagency Committee on Smoking and Health established under subsection (b), coordinate the activities of the Federal Government referred to in paragraphs (1) and (2) of this subsection with similar activities in the private sector;

(4) conduct research and develop new methods for informing the public of the effects of smoking on health, either independently or in conjunction with the private sector, for use in a national effort;

(5) collect, analyze, and disseminate information, studies, and other data related to smoking and its effects on health;

(6) make available, through specific publications and bibliographic and reference materials, information on research efforts relating to smoking and its effects on health; and

(7) undertake any other additional informational and research activities which the Secretary determines necessary and appropriate.

In carrying out the requirements of this subsection, the Secretary shall seek to develop methods of communication with Federal, State, and local entities, as well as with the private sector.

(b)(1) To carry out the activities described in paragraphs (2) and (3) of subsection (a), there is established an Interagency Committee on Smoking and Health. The Committee shall be composed of repre-

sentatives from appropriate institutes and agencies of the Department, which may include the National Heart, Lung, and Blood Institute, the National Cancer Institute, the National Institute of Child Health and Human Development, the Health Resources and Services Administration, and the Centers for Disease Control.

(2) The Committee shall meet at least four times each year.

(c) The Secretary shall transmit a report to Congress not later than January 1 of each year which shall contain—

(1) current information on the effects of smoking on health;

(2) an overview and assessment of Federal activities undertaken to inform the public of the effects of smoking on health;

(3) information regarding the activities of the private sector with respect to the effects of smoking on health; and

(4) such recommendations for legislation as the Secretary may consider appropriate.

ADDITIVE INFORMATION REQUIRED

SEC. 1712. (a)(1) It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes unless such person has provided to the Secretary a complete list of each chemical additive used in the manufacture of such cigarettes and the relative quantity of such additives.

(2) The Secretary and any officer or employee of the Department shall not disclose to any person outside the Department any information received pursuant to paragraph (1).

(3) For purposes of section 522(b)(4) of title 5, United States Code, and section 1905 of title 18, United States Code, any information received by the Secretary or any officer or employee of the Department pursuant to paragraph (1) shall be considered to be a trade secret.

(b) Any person who violates the provisions of subsection (a)(1) of this section shall be guilty of a misdemeanor and shall, upon conviction thereof, be subject to a fine of not more than $10,000.

(c) Upon application of the Attorney General of the United States, the district courts of the United States shall have jurisdiction, for cause shown, to prevent and restrain violations of subsection (a)(1) of this section.

(d) At such times as the Secretary considers appropriate, but not less than annually, the Secretary shall transmit to the Congress a report which shall include a complete listing of chemical additives used in the manufacture of cigarettes based on the additive information required to be submitted under subsection (a)(1), a summary of research activities and research findings on the health risks associated with such additives, information pertaining to any such additive or additives which in the judgment of the Secretary pose an additional health risk to cigarette smokers, and any other information which the Secretary determines to be in the public interest, except that no information contained in any such report shall identify which individual additives are used in any specific brand of cigarettes or by any specific person who manufactures cigarettes, imports cigarettes, or packages cigarettes for sale or distribution within the United States.

* * * * * * *

FEDERAL CIGARETTE LABELING AND ADVERTISING ACT

(PUBLIC LAW 89-92, APPROVED JULY 27, 1965)

AN ACT To regulate the labeling of cigarettes, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Cigarette Labeling and Advertising Act".

* * * * * * *

[LABELING

[SEC. 4. It shall be unlawful for any person to manufacture, import, or package for sale or distributing within the United States any cigarettes the package of which fails to bear the following statement: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health". Such statement shall be located in a conspicuous place on every cigarette package and shall appear in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the package.]

PUBLIC AWARENESS STATEMENT

SEC. 4. (a)(1) It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes, the package of which fails to bear the following statement: "WARNING: Cigarette smoking causes CANCER, EMPHYSEMA, and HEART DISEASE; may complicate PREGNANCY; and is ADDICTIVE."

(2) The labeling statement required under this subsection shall be located in a conspicuous place on every cigarette package and shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.

(b)(1) It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes, the package of which fails to disclose the level of—

(A) tar;

(B) nicotine; and

(C) carbon monoxide;

contained in such cigarettes.

* * * * * * *

REPORTS

SEC. 8. [(a) The Secretary of Health, Education, and Welfare shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter concerning (A) current information in the health consequences of smoking, and (B) such recommendations for legislation as he may deem appropriate.]

[(b)] The Federal Trade Commission shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (A) the effectiveness of cigarette labeling, (B) current practices and methods of cigarette advertising and promotion,

and (C) such recommendations for legislation as it may deem appropriate.

* * * * * * *

XI. ADDITIONAL VIEWS OF MR. QUAYLE

I voted "present" on this legislation when it was reported by the Labor and Human Resources Committee. I strongly support further educational efforts to inform the public of the dangers of smoking, particularly efforts directed towards young people and others who are especially at risk, and I believe that further research into the health consequences of smoking are clearly warranted. However, I believe that we would have a stronger bill and one more likely to be enacted into law, if we provided limited additional time for further negotiation between the industry and the Assistant Secretary for Health of the Department of Health and Human Services.

Much progress was made in such negotiations between the time that I suggested them and the time that the Committee reported the bill. I believe that an agreement, concerning both labeling and disclosure, can be worked out and that such an agreement will best protect the public health and ensure that the industry is not subjected to unnecessary burdens.

Initial negotiations between the tobacco industry and the Assistant Secretary for Health resulted in an agreement that a single, strong warning label could replace the rotating labels provided for in the original bill. The Committee adopted an amendment to provide a single (though different) label and I voted in favor of that amendment. I believe similar constructive changes in the legislation can result from further negotiations and that only with such negotiations can we enact more effective protection into law.

DAN QUAYLE.

XII. MINORITY VIEWS OF MR. EAST

The Smoking Prevention Health and Education Act goes far beyond being informational, beyond dealing with genuine health concerns. It is punitive and over-regulatory. And the manner in which it was voted out of this Committee was unfair to the tobacco industry which had negotiated in good faith.

At the request of Committee members, the Chairman sent the leaders of this great and honorable industry off to negotiate in good faith with the Department of Health and Human Services. "I am interested in stronger labeling," the Chairman said. "I am interested in voluntary approaches . . . I would like to see it resolved that way. I have no secrets about that."

"It would be preferable to me to have you feel," the Chairman told cigarette company executives, "that the process has served you as well as I feel the process will serve the people" (S. tr. p. 123, 5/12).

None on the Committee, certainly not I, could disagree with that statement. But I for one strongly disagree with what the Committee did next. After weeks of negotiations, Assistant Health Secretary Edward N. Brandt came back with a single label which had been proposed by HHS and acceded to by the industry in its desire to meet the deadline imposed by the Chairman.

"This was the HHS's position," said Mr. Kornegay, "and after a lot of debate and a lot of consideration by the industry, we said we would go along with it . . . We had been meeting over a period of several weeks, and we were getting closer and closer, and we finally gave in on it and said we would go along with it" (S. tr. p. 14, 6/22).

The industry "gave in" to the HHS proposal in the sort of good faith negotiations the Chairman and Committee members indicated they wanted. It had carried out its side of the bargain.

Ignoring the good faith effort of that industry and HHS, the Committee threw aside the single, "stronger" warning label produced after much labor. They discarded with little or no discussion:

> SURGEON GENERAL'S WARNING: Smoking Increases Your Risk of Cancer and Heart, Lung and Other Serious Diseases.

In almost less time than it takes to tell, an entirely new and previously unconsidered substitute warning label was presented by a Committee member who had not even participated in the hearings: Adopted on the spot was:

> Warning: Cigarette smoking causes CANCER, EMPHYSEMA, HEART DISEASE; may complicate PREGNANCY; and is ADDICTIVE.

Compounding the error was the fact that the substitute label differs starkly from the bill's "findings," the accuracy of which was at issue during the two days of hearings. The Chairman himself observed that the "findings" were taken right out of the Surgeon General's report. His point is essentially correct, although that does not make the "findings" themselves correct.

Such a clear statement of the source should at the very least compel the language of any statutory health warning to note the source, as indeed the current label does. If we fail to do that, we deliberately mislead the reader of that label.

So on the one hand we have a set of "findings" about which there are very strong differences of opinin among very respected members of the scientific community. This alone suggests a caution, a "go-slow" sign, about precisely what we do and do not know about the relative health risks of smoking. On the other we have a warning—precipitously discarded—that was drafted after much study by the nation's top federal health authorities.

But the Committee chose to ignore HHS and went instead with a last-minute substitution that badly overstates the Surgeon General's "findings" which they accepted in voting out the bill.

The Committee also chose to ignore the judgement of the HHS experts that HHS did not need the help of a statutorily established Interagency Committee on Smoking and Health and federally mandated public disclosure of the cigarette manufacturers' competitive trade secrets. Dr. Brandt made it quite clear in House and Senate hearings this year and last that HHS felt it had the situation in hand with its current structure. He reminded the Committee of the voluntary agreement in effect with the industry since last year to provide HHS protected information on cigarette additives.

Let the record show that the Committee members, agreeing to report out S. 772 in its present form, cannot truly have considered the hearings record. I challenge anyone to read the entire record of these hearings and come to a conclusion that either the "findings" or the label is justified or to conclude that a new open-ended, anti-smoking bureaucracy at HHS and mandatory cigarette ingredients disclosure are warranted or wise, especially if HHS neither needs nor wants them.

The Chairman has stressed throughout the hearings his desire to be fair. And yet, in the final analysis, the Committee has been grossly unfair to the tobacco industry. The Committee has been unfair to the public servants at HHS whom directed to negotiate and who spent weeks seeking a resolution. But the Committee has been most unfair to the American public, who would most have benefited from a new spirit of voluntarism.

UNSUBSTANTIATED "FINDINGS" ABOUT SMOKING

The "findings" is S. 772 are not substantiated by fact. Here, briefy, is what eminently qualified witnesses had to say about them in hearings before this Committee and in testimony this year on a similar bill, H.R. 1824, for the Subcommittee on Health and the Environment of the House Energy and Commerce Committee.

(1) Cigarette smoking is tied to "the unnecessary deaths of over 300,000 Americans annually"

"Arbitrary extrapolations from a very doubtful data base"—Hans J. Eysenck, Ph. D., University of London, H. tr. p. 148, 3/17.

"The original Surgeon General's committee [on smoking and health] said that too many assumptions had to be made in order to decide how many deaths might be attrributed to smoking. But the Surgeon General . . . did not take their advice and he . . . came up with 300,000."—Sheldon C. Sommers, M.D., Council for Tobacco Research, H. tr. p. 175, 3/17.

"Responsible leaders in government have to take every care to avoid sponsoring legislation like this which implies that they know the cause of lung cancer and could reduce deaths by 300,000 or any arbitrary unprovable number by passing a law."—Prof. Eleanor J. Macdonald, University of Texas (emeritus), p. 2.[1]

"Might well have the effect of reducing the scientific interest in researching the many unknown facets relating to the causes of the disease in question."—Leon O. Jacobson, M.D., Council for Tobacco Research, p. 8.

(2) Cigarette smoking is the "primary cause of lung cancer and emphysema"

"Based, in large part, upon unwarranted extrapolation of ambiguous epidemiological data."—Gerhard N. Schrauzer, Ph. D., University of California, p. 2.

"I do not agree with the 'findings'."—Katherine McD. Herrold, M.D., U.S. Public Health Service (retired), p. 4.

"The statements . . . regarding lung cancer are not scientifically justified."—Arthur Furst, Ph. D., University of San Francisco (emeritus), p. 2 of letter.

"Several witnesses . . . referred to a 'beagle dog study' as providing confirmatory evidence . . . The study has been severely criticized in the scientific literature and to my knowledge is no longer relied on nor even cited by serious researchers."—Victor B. Buhler, M.D., Liberty, Mo., p. 1 of letter filed with the House Committee.

"It has not been scientifically established that cancer of any type is caused by cigarette smoking."—Mariano LaVia, M.D., Medical University of South Carolina, p. 2.

"Cigarette smoking is not 'the primary cause' of pulmonary emphysema."—Domigo M. Aviado, M.D., University of Medicine and Dentistry of New Jersey, p. 16.

"Pulmonary emphysema . . . is part of the aging process. I don't think a person with emphysema should smoke, but I don't believe that smoking causes the emphysema."—William B. Ober, M.D., Hackensack, N.J., p. 2.

"The purported 'finding' that cigarette smoking is a 'major cause' of emphysema is scientifically unfounded."—Robert C. Hockett, Ph.D., Council for Tobacco Research, p. 8.

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[1] Citations not labeled with a "tr. p." number are excerpted from statements filed with the Committee and are not found in the actual transcript of the Committee and are not found in the actual transcript of the Committee hearings. Those labeled "H. tr." are from the official transcript of hearings on H.R. 1824 before the House Subcommittee on Health and the Environment. Those labeled "S. tr." are from the unofficial transcript of the Labor and Human Resources Committee hearings.

(3) "One-third of the deaths attributable to cardiovascular disease are associated with smoking"

"In the most recent study from the Mayo Clinic . . . over 15,000 patients with coronary artery disease . . . were studied. No positive correlation . . . occurred between arteriographic measures of disease and the cigarette smoking history."—Dr. Eysenck, H. tr. p. 157, 3/17.

"There is no experimental proof."—Richard J. Bing, M.D., University of Southern California (emeritus), p. 5.

"No studies have been done that demonstrate scientifically that smoking is a cause of coronary heart disease."—Edwin R. Fisher, M.D., Univerisity of Pittsburgh, H. tr. p. 116, 3/17.

"After six years of follow-up, there was no significant difference in the overall rate of cardiovascular mortality between the intervention group and the usual care group [in the government's $115 million 'MRFIT' study of 12,000 men], even though there was a two-to-one reduction of smoking in the intervention group compared to the usual care group.—Dr. Fisher, H. tr. p. 117, 3/17.

"These intervention studies find that cessation of smoking will not lead to a reduction of coronary heart disease. Moreover, they are inconsistent with the hypotheses that smoking causes coronary heart disease."—Dr. Fisher, H. tr. p. 118, 3/17.

"The matter of cigarette smoking cessation in the MRFIT program deserves special attention . . . the absence of any 'beneficial effect' on heart disease mortality was completely 'unexpected' and caused 'surprise' and consternation."—Carl C. Seltzer, Ph.D., Harvard University, appendix, pp. 4–5.

(4) "The risks of miscarriage, stillbirths, premature births, and child weight deficiencies for pregnant women who smoke are higher . . . "

"This contradicts well established medical knowledge . . . The statements rest on no scientific foundation and have no probative value."—Dr. Ober, p. 2.

"As far as birthweight deficiencies in smokers are concerned, I have direct evidence that smoking is not the cause."—L.G.S. Rao, Ph.D., biochemist specializing in perinatal medicine, Glasgow, p. 4.

"This field is controversial, still developing and the evidence in the literature and at these hearings cannot be regarded as conclusive."—Dr. Sommers, H. tr. p. 141, 1/17

(5) "Present Federal, State and private initiatives have been insufficient" in informing the public

"The premise is wrong. The proposed strategy is wrong."—Larry Light, Ph.D., Ted Bates Advertising, H. tr. p. 42, 3/17.

"I do disagree with the principle that if consumers do not behave as you behave, then they must be uninformed. if they do not choose as you would choose, then they must be ignorant. If they do not believe as you believe, then they must be unaware."—Dr. Light, H. tr. P. 45, 3/17.

"This assumption is unfounded."—Roger D. Blackwell, Ph.D., Ohio State University, H. tr. p. 66, 3/17.

"What new strategy . . . could increase the saturation coverage of the smoking and health issue? . . . Every stratum of society . . . is barraged with information."—Prof. Macdonald, p. 1.

"Today more than nine out of ten Americans believe that smoking is hazardous to a smoker's health. In a true sense the Surgeon General's warning has pervaded our culture."—Eric Rubin, Counsel, Outdoor Advertising Association of America, p. 2.

LEGISLATING SCIENCE

The "findings" in S. 772 are among the frequent incantations of the many anti-smoking groups who engineered and then supported the legislation. Passage of S. 772 would elevate the slogans of anti-cigarette activists to official legislative "findings"—in spite of testimony to the contrary this year and last.

The Chairman praised "the very excellent backgrounds" of the scientists who disputed the "findings" (S. tr. p. 95, 5/12). He admitted "We have a differing perspective, a differing viewpoint" (S. tr. p. 96, 5/12). But thereafter he and other Committee members voted the controversial litany a Committee imprimatur, although as legislators, not medical men, we are hardly qualified to evaluate the state of scientific knowledge in smoking and health.

THE CASE AGAINST AN EXPENSIVE NEW STOP-SMOKING BUREAUCRACY

The Smoking Prevention Health and Education Act would require HHS to set up smoking and health research and "educational" programs; to coordinate all government anti-smoking activity; to set up an Interagency Committee on Smoking and Health; and make various reports to Congress.

The bill, however, contains no specific authorization for new appropriations. Its silence on this crucial question provides HHS with at least two advantages:

(a) It eliminates any need to obtain Budget Act waivers for consideration of the measure after the deadline for reporting authorizations (May 15); and

(b) It constructively provides open-ended spending authority for the HHS Secretary's activities in the anti-smoking campaign.

Ultimately, the only limitation on the Secretary's activities under S. 772 will be provided by the appropriations process.

And look what HHS said of the bill and its stated purpose of "improving public awareness of the health consequences of smoking." Dr. Brandt told the Committee, "We do not believe that the warning label . . . by itself . . . is going to be sufficient" (S. tr. p. 59, 5/5). He also said, "We need to expand our cooperative effort with other Federal, State and local governments and with the private sector . . ." (S. tr. p. 38, 5/5).

At what cost? And is research and "education" in other areas of HHS responsibility likely to suffer if no more funds are forthcoming for these "expanded" HHS efforts against cigarettes?

Dr. Brandt was candid in admitting HHS did not need the new Interagency Committee on smoking and Health, a cornerstone provision of S. 772. "We do not believe that the creation of the interagency committee, as specified in this legislation, is necessary legislatively because, in the first place, we have such a committee oper-

ational now. Secondly, any changes that need to be made in such a committee or in its functions could be done administratively" (S. tr. p. 57, 5/5).

Nor was there indication that HHS thought it necessary to have a law such as S. 772. Brandt stopped short of recommending its passage. Although he did not specifically argue against it, he is on the record with these two thoughts:

"The educational efforts, short of labeling, can certainly be done, and are being done, under existing law" (S. tr. p. 63 5/5).

"I think that clearly it is preferable to have the Government and the industry in agreement and with the industry regulating itself and working with the Government in a cooperative way . . . the preferable way to go" (S. tr. p. 67, 5/5).

Nor would Dr. Brandt make recommendations on S. 772 provisions that would force cigarette manufacturers to reveal the names and quantities of ingredients used in their cigarettes, traditionally a closely held trade secret, to HHS, which, in turn, would have to report that proprietary information at least annually to the Congress.

Said Brandt:

"We cannot be very precise about the health hazards or lack thereof of any particular substances" (S. tr. p. 52, 5/5).

"The Department has negotiated an agreement with the six major cigarette companies which permits us to learn the identities of substances commonly added to cigarettes. . . . That has not run its course yet" (S. tr. p. 39 and 64, 5/5).

Brandt was positive on one aspect of labeling. "We want to be clear," he declared under questioning, "that in our advocacy of stronger warnings that we would certainly want to be scientifically accurate and (b) to be effective at informing and educating the public so that they can make intelligent decisions." (S. tr. p. 73, 5/5).

How Accurate, How Effective Is S. 772's Warning Label?

Dr. Brandt, one of the highest health officials in government, spent untold hours endeavoring to settle upon a single warning label. Dr. Brandt is the boss of the U.S. Surgeon General of the Public Health Service, upon whose yearly reports S. 772's "findings" are said to be based.

Yet, how closely does the wording of the substitute warning label agreed upon so hastily by Committee members track those of the five "findings"?

Is not the last minute label amendment, voted without benefit of counsel from Dr. Brandt and HHS, an overstatement of scientific knowledge?

The most egregious and blatant misuse of scientific fact in the voted label, however, must be the reference to cigarette smoking as "addictive." Even the witness who appeared with Dr. Brandt, Dr. William Pollin, director of the National Institute on Drug Abuse, admitted "evidence is not yet conclusive as to whether or not there is physiologic dependence or what type of withdrawal syndrome is associated with cigarette smoking" (statement, p. 2).

Theodore H. Blau, clinical and consulting psychologist from Tampa, a past president of the American Psychological Association, wrote in submitted testimony on the original bill: "Legislating a medical label of 'addiction' as applicable to cigarette smoking is not scientifically justified . . . Despite this intense scientific focus on the behavorial as well as the physiological aspects of cigarette smoking, no general agreement among scientists exists as to the question of whether cigarettes or their contents are addictive" (statement pp. 4-5).

Again and again, Dr. Brandt stressed in his testimony the Department's desire that any warning label decided upon be accurate as well as effective.

Let the record show that the label voted by the Committee is not accurate and therefore is misleading. It cannot be effective in providing means for the "informed decisions concerning smoking" stated as the purpose of the bill.

CONCLUSION

The Smoking Prevention Health and Education Act is bad legislation, arrived at by the Committee in a manner to be deplored by fair minded Members of the Congress.

It is unnecessary, inequitable, potentially counter-productive and over-regulatory and could wreak irreparable damage not only on an old and honorable industry but on our system of government.

The Americans are informed, and they make the informed decision to use or not to use tobacco products as a matter of personal right.

S. 772 will substantially increase the cost of the government's anti-smoking campaign by requiring new bureaucracy, new information campaigns against smoking, and additional regulatory efforts. Ultimately it will increase the cost of cigarette production to the detriment of consumers already hard hit by the decision of the last Congress to double the cigarette excise tax.

The specific labeling statement required by the bill is not substantiated by proof.

The so-called Congressional "findings" are no more than assumptions—but the general public will never know that such assumptions are not absolute fact. In litigation and in state and local governing bodies, the Congressional findings will be cited again and again in support of anti-tobacco initiatives.

The bill does not directly amend the Federal Trade Commission's authority with respect to the regulation of cigarette advertising practices. Nevertheless, the terms of S. 772 are a significant threat to the manufacturers' Constitutionally protected commercial speech rights. Using the terms of S. 772 as precedent, the Federal Trade Commission could use its general authority under section 5 of the FTC Act to impose additional and burdensome disclosure and "warning" requirements on billboards and advertisements in the print media.

There is no other product, lawfully manufactured and sold in the United States, that is subject to such burdensome requirements as

proposed in S. 772. This legislation must be rejected by Congress as unwarranted and excessive intrusion into the marketplace.

JOHN P. EAST.

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